IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

)	
CARDIONET, INC.)	
227 Washington Street)	
Conshohocken, PA 19428)	
and)	
)	
LIFEWATCH SERVICES, INC.)	
O'Hare International Center, II)	Civil Action No
10255 West Higgins Road)	
Rosemont, IL 60018)	Jury Demand
Plaintiffs,)	
)	
v.)	
)	
CIGNA HEALTH CORPORATION)	
900 Cottage Grove Road)	
Bloomfield, CT 06002)	
)	
Defendant.)	

COMPLAINT

Plaintiffs CardioNet, Inc. ("CardioNet") and LifeWatch Services, Inc. ("LifeWatch") file this Complaint against Defendant CIGNA Health Corporation ("CIGNA") on their own behalves and as assignees of the rights and claims of patients enrolled in CIGNA health plans, and allege as follows:

NATURE OF ACTION

1. CardioNet and LifeWatch (collectively, "Plaintiffs") are leading suppliers of outpatient cardiac telemetry services ("OCT"). OCT services have been ordered by physicians, most typically cardiologists, for hundreds of thousands of patients over the past ten years to diagnose or rule out suspected clinically significant arrhythmias which pose a risk of stroke or heart disease. OCT services are used to detect suspected arrhythmias that are not

capable of being diagnosed with other older forms of ambulatory ECG monitoring devices. If undetected and untreated, certain arrhythmias, such as atrial fibrillation, can be fatal.

- 2. OCT technology has been approved by the Food and Drug Administration ("FDA") for well over a decade. It also has been routinely covered for years by Medicare (which insures approximately 60 million individuals), as well as by many major commercial insurers (such as, for example, Aetna).
- 3. CIGNA had covered OCT services for its policy holders since 2007 through contracts with both CardioNet and LifeWatch. Beginning in 2007, CIGNA issued formal coverage policies that established standardized "coverage" of OCT services for all patients insured by CIGNA based on extensive, peer-reviewed medical literature. That policy was reaffirmed in CIGNA's 2011 Cardiac Event Monitor Coverage Policy (the "2011 CEM Policy").
- 4. This action is brought to challenge CIGNA's recent and sudden reversal of its longstanding and consistent coverage of Plaintiffs' OCT services through an October 2012 CEM Coverage Policy (the "2012 CEM Policy"). The 2012 CEM Policy declared that OCT was not covered for CIGNA plan members on the stated basis that OCT was considered "experimental, investigational and unproven (EIU)."
- 5. CIGNA's 2012 coverage policy reversal both endangers patients who are at risk for heart attack or stroke and is unsupportable by law. In stating in the 2012 CEM Policy that "there is insufficient evidence in the medical literature supporting the clinical utility of" OCT services, CIGNA relied on the exact same medical literature which it had cited in its 2011 Coverage Policy and in earlier policies as the basis for reaching the exact opposite conclusion. CIGNA not only cited the exact same medical evidence as its basis for diametrically opposite conclusions about whether OCT was EIU, but it ignored additional and more recent medical

literature that further demonstrated the clinical utility of OCT. On information and belief, CIGNA's reversal of its coverage policy was purely financially motivated, and therefore facially suspect under controlling case law.

- GIGNA separately distributed an August 2012 Medical Coverage Policy Updates (the "Physician Updates") to hundreds of thousands of physicians who participate in CIGNA's national provider network, which represented that: "We will not cover an external mobile outpatient cardiac telemetry system . . . for any indication because it is considered EIU [experimental, investigational or unproven]." This unqualified assertion is false and misleading because OCT technology is widely accepted in the medical community and not considered EIU, and because CIGNA is required to cover OCT when administering employer health benefit plans that do not circumscribe coverage as narrowly as CIGNA's 2012 CEM Policy. Not surprisingly, the Physician Updates has impaired Plaintiffs' existing and prospective relations with treating physicians, while simultaneously jeopardizing the health and well-being of CIGNA policy holders.
- 7. Through this action, Plaintiffs seek to reinstate coverage for OCT services on behalf of patients whose health benefits have been arbitrarily limited by CIGNA to exclude coverage of OCT. Plaintiffs advance these claims under both ERISA and common law based on assignments of the rights and claims of plan participants and beneficiaries whose rights they represent. More broadly, Plaintiffs seek to prevent the further application of the 2012 CEM Policy to CIGNA plan participants and beneficiaries through declaratory and injunctive relief.
- 8. Plaintiffs also seek financial relief and equitable recourse against the deterrent effects and corresponding financial injuries they are suffering as a result of the Physician Updates. The Physician Updates is false and misleading, and has had the practical

effect of widely discouraging doctors from ordering OCT services for their patients for which the OCT is medically necessary and appropriate.

JURISDICTION AND VENUE

- 9. This action arises in part under the Employee Retirement Income Security Act, 29 U.S.C. § 1001 *et. seq.* ("ERISA"), and seeks relief pursuant to 29 U.S.C. §§ 1132(a)(2) & (3), and attorney's fees and costs under 29 U.S.C. § 1132(g).
- 10. This action arises in part under the Lanham Act, 15 U.S.C. § 1051 *et seq*. This Court has authority to decide a civil action pursuant to 15 U.S.C. § 1115(a), and to grant injunctive relief pursuant to 15 U.S.C. § 1116.
- 11. Jurisdiction is proper under 28 U.S.C. § 1331 because this case arises under the laws of the United States.
- 12. This Court has authority to grant declaratory relief pursuant to 28 U.S.C. §§ 2201 and 2202.
- 13. The Court has supplemental jurisdiction over the State law claims for breach of contract, and tortious interference with financial relationships pursuant to 28 U.S.C. § 1367.
- 14. Venue is proper in this judicial district under 28 U.S.C. § 1391 because CIGNA resides within this judicial district, this jurisdiction represents Plaintiff CardioNet's principal place of business, LifeWatch provides services for CIGNA patients within this jurisdiction, and a substantial part of the events giving rise to the claims herein occurred within this judicial district.

PARTIES

15. Plaintiff CardioNet is a corporation organized under the laws of Delaware. Its principal place of business is Conshohocken, Pennsylvania. CardioNet manufactures and

supplies OCT devices under the trade name of Mobile Outpatient Cardiac Telemetry, or "MCOT." CardioNet historically has operated a facility located in Conshohocken, Pennsylvania, from which it monitors and reviews data output from MCOT devices (which it then transmits to treating physicians nationally when arrhythmias are detected). More recently, CardioNet established a second monitoring center in San Francisco, California.

- 16. Plaintiff LifeWatch is a corporation organized under the laws of Delaware and is headquartered in Chicago, Illinois. LifeWatch provides OCT services for detecting arrhythmias under the trade name of Lifestar Ambulatory Cardiac Telemetry (or "ACT"). LifeWatch has business operations or facilities located in Philadelphia, Chicago, and San Francisco, from which its employees monitor and review data output from LifeWatch's OCT devices (which is then transmitted to treating physicians nationally when arrhythmias are detected).
- 17. Defendant CIGNA is a health care insurer. Among other things, CIGNA sells insurance, or underwrites or administers ERISA-regulated health and welfare benefits plans, nationally, including in the Commonwealth of Pennsylvania. On information and belief, CIGNA is incorporated in Delaware, and has its principal place of business in Hartford, Connecticut.

FACTUAL ALLEGATIONS

Outpatient Telemetry Services

- 18. OCT services are prescribed by treating physicians, and mostly by cardiologists, to diagnose or rule out clinically significant arrhythmias which can indicate risk of stroke or heart disease, or to detect post-surgical problems.
- 19. Arrhythmias are changes in the heart's normal rate or rhythm. They are classified by their location in the heart and by their speed or rhythm. Certain arrhythmias, such as atrial fibrillation, can have serious and even fatal consequences if undetected and untreated.

- 20. This action requires an appreciation of the relationship of OCT to certain predecessor technologies used to diagnose heart arrhythmias, including Holter monitors and cardiac event monitors (or "CEMs").
- 21. Holter monitors are portable recording devices attached to patients by leads. They continuously record ECGs over a relatively short period of time, typically 24 to 48 hours. Holter monitors, however, are ineffective for diagnosing cardiac arrhythmias if a patient experiences infrequent arrhythmias.
- 22. A conventional cardiac event monitor can be used for longer spans of time than a Holter monitor. Event monitors generally are patient activated, and ordinarily must be manually connected to a telephone line to transmit recorded data to a monitoring facility. Aside from the additional disadvantage of requiring patient initiation and manual transmission of EKG data, event monitors use algorithms that are far less sophisticated at detecting arrhythmias than beat-to-beat OCT services.
- 23. OCT is the outpatient (or ambulatory) equivalent of telemetry services provided in a hospital telemetry unit, and is effective for detecting arrhythmias that evade detection with Holter monitors or conventional event monitors.
- 24. With OCT, a recording device is connected to the patient by a three-lead sensor. A transmitter, worn around the neck, constantly communicates with a lightweight monitoring unit carried by the patient. Although OCT generally is used for periods of up to 30 consecutive days, arrhythmias often are detected sooner typically between 10 and 14 days at which point real-time monitoring is discontinued.
- 25. When an arrhythmia is detected, an OCT device automatically and wirelessly transmits electrocardiograchic ("EKG") data to a remote central recording station,

where it is analyzed on a near real time basis by trained and certified technicians, who forward results to the ordering physician.

26. Physicians who order OCT services for their patients request the level and timing of responses from the monitoring technician, which can range anywhere from daily reports to immediate (stat) results under defined parameters. Life threatening events are reported in all cases, and regardless of the parameters set by the ordering physicians.

Acceptance of OCT in the Medical Community

- 27. FDA has long approved OCT technology as safe and effective for detecting cardiac arrhythmias. OCT technology has been recognized and approved specifically by the FDA for use in cases where a patient's symptoms which may including syncope, presyncope or severe palpation are suggestive of clinically significant arrhythmias, but occur less frequently than every 24 hours.
- 28. CardioNet received FDA premarket approval for MCOT in February 2002 based on the prior approval of a substantially equivalent "predicate device." LifeWatch's OCT first received 510(k) premarket approval from the FDA in August 2006 as an electrographic transmitter and receiver; the FDA corrected its premarket approval of the LifeWatch OCT in March 2007 to reflect its additional status as an arrhythmia detector and alarm.
- 29. In addition to having been long approved by the FDA, OCT is covered by Medicare. Medicare is the nation's largest single health insurer, and "covers" approximately 50 million individuals. Once a service is "covered" by the Medicare fee-for-service program, it also is automatically covered by Medicare HMOs (known as Medicare Advantage plans).
- 30. A diagnostic device or test is "covered" by Medicare only if it is ordered by a physician for the use for which the technology has been approved by the FDA and is

deemed to be a medically reasonable and necessary and generally accepted by the medical community.

- 31. Medicare initially began covering OCT (under "Part B" of the Medicare program) on a case specific basis as early as 1998.
- 32. A service also can be covered by Medicare systemically for pre-specified classes of cases. This is accomplished through the issuance of a Medicare national or local coverage determination (and "NCD" or "LCD"), which obviates the need for case-by-case coverage determinations.
- 33. Medicare Administrative Contractors ("MACs") with jurisdictional over claims emanating from monitoring facilities operated by Plaintiffs have issued formal coverage determinations establishing OCT as "covered" service in designated classes of cases.
- 34. Highmark Medicare Services (which was succeeded by "Novitas") exercised jurisdiction for OCT monitoring services in the multi-state region that has included at least Pennsylvania, Delaware, New Jersey, Maryland, the District of Columbia. Highmark issued an LCD covering "real-time, outpatient cardiac telemetry," including MCOT and ACT, effective in 2002, which was revised as recently as June 29, 2011.
- 35. Under the Highmark LCD, coverage of OCT extends "to patients who have demonstrated a specific need" for continuous long term (over 24 hour) "cardiac surveillance . . . in order to identify and document a suspected and/or paroxysmal dysrhythmia," based on specified documentation by the "ordering physician." This includes cases where "other testing and/or monitoring/recording/telemetry has been unrevealing," and the patient's record "demonstrates that the results of this testing will provide diagnostic and/or treatment information useful in the ongoing management of the patient."

- 36. Palmetto Government Benefits Administration, which has jurisdiction over claims for OCT monitoring services performed by Plaintiffs in California, issued an LCD covering OCT services on or around August 20, 2008. Palmetto's LCD was recently revised, and further liberalized for coverage of OCT services performed on or after October 25, 2012.
- 37. Medicare Part B coverage of OCT (which includes OCT provided through hospitals) also has been approved by another MAC, Wisconsin Physician Services, since on or around January 15, 2007.
- 38. In issuing systemic coverage determinations for OCT, the Medicare MACs were required to make formal, evidence-based determinations that OCT is "reasonable and necessary for the diagnosis" of symptomatic transient arrhythmias when the frequency of symptoms is limited, and for asymptomatic patients at risk for clinically significant arrhythmias that are unlikely to be captured or documented by short term recording devices. As a predicate for issuing a coverage determination, a Medicare MAC, statutorily, is relevantly required to render a finding that the service at issue is not considered to be experimental.
- 39. CardioNet was enrolled in the Medicare program as a provider type known as an Independent Diagnostic Testing Facility (an "IDTF") and issued a Medicare provider number enabling it to bill Medicare for MCOT effective February 1, 2002.
- 40. LifeWatch was enrolled by the Medicare program an IDTF and was issued a Medicare provider number to bill Medicare for ACT effective October 2, 2006.
- 41. Diagnostic devices are billed to Medicare (and other payers) based on Common Procedural Terminology ("CPT") codes, which are adopted and copyrighted by the American Medical Association ("AMA") based on recommendations of national, medical advisory committees.

- 42. Initially, OCT services had been billed by Plaintiffs, under instructions of third party payers, under certain "shared" or miscellaneous CPT codes also used for other cardiac monitoring technology. OCT services were assigned dedicated procedure codes by the AMA coding committee in January 2009 (i.e., 93229 for the "technical" services, and 93228 for a physician's professional interpretation of OCT data).
- 43. In assigning unique CPT codes for OCT services, the AMA acted on the recommendation of the American College of Cardiology, which, in turn, relied on clinical studies demonstrating the enhanced clinical/diagnostic value of OCT as compared to older and less sophisticated devices, such as a Holter monitor or ambulatory, patient activated CEMs.
- 44. Currently Medicare pays a single case rate for the technical services for OCT that covers up to 30 days of service (although the average duration for monitoring needed to detect an arrhythmia is closer to 14 days).
- 45. OCT also has been widely covered by commercial insurers. For example, Aetna Health, Inc., issued a comprehensive Clinical Policy Bulletin providing for standardized coverage of OCT to document arrhythmia "instead of a Holter monitor, or if a Holter monitor fails to document a suspected arrhythmia." Policy Bulletin No. 0073 (as reviewed on May 22, 2012). Like Medicare, "Aetna considers mobile cardiac telemetry . . . medically necessary for evaluation of recurrent episodes of pre-syncope, syncopes palpitations, or dizziness" when arrhythmia is suspected and occurs "less frequently than daily." <u>Id.</u>

CIGNA's Coverage of OCT

46. LifeWatch entered into an Ancillary Services Agreement ("ASA") with CIGNA to provide OCT to CIGNA plan members effective June 15, 2007. That agreement was most recently amended effective March 2, 2009.

- 47. CardioNet entered into an ASA with CIGNA to provide OCT to CIGNA plan members effective August 1, 2007. That agreement was most recently amended effective September 2011.
- 48. Each ASA includes a reimbursement page specifically setting forth a maximum allowable fee for OCT.
- 49. Both ASAs relevantly define "Covered Services" as "those health care services for which a Participant is entitled to receive coverage under the terms and conditions of Participant's Benefit Plan."
- 50. The contracted "Covered Services" provided by Plaintiffs include patient hookup and instruction by analysis of transmitted EKG data and reporting of monitoring results to treating physicians who interpret the data for purposes of diagnosing and managing the care of the patient.
- 51. "Coverage" of OCT services for patients also separately includes (under CPT Code 93228) the professional services of physicians who interpret the EKG data.
- 52. CIGNA provides reimbursement for a Covered Service as long as it is considered medically necessary in a given case. Both of Plaintiffs' ASAs define "Medically Necessary" as "services and supplies that satisfy the Medical Necessity requirements under the applicable Benefit Plan," and both recognize OCT as billable under CPT Code 93229.
- 53. The ASAs provide that payments for Covered Services provided by Plaintiffs, shall be made directly by CIGNA to Plaintiffs as in-network providers.
- 54. From August 2007 through September 2012, CardioNet routinely billed CIGNA, and CIGNA routinely covered charges for MCOT services provided to participants in standard CIGNA health plans and other employer health plans administered by CIGNA.

- 55. In a policy that became effective April 15, 2007, CIGNA pronounced, based on the latest medical literature, that it would henceforth cover home-based real-time surveillance systems for diagnosis of "clinical suspicion of a significant, but non-life threatening, arrhythmia" with "symptoms of syncope presyncope, or sever palpitations occurring less frequently than once per 24 hours."
- 56. Citing the FDA's approval of such devices dating back to 1998, the subsequent FDA approval of devices manufactured by, *inter alia*, CardioNet and LifeWatch, and a variety of peer-reviewed medical studies, CIGNA found *as of 2007* that: "There is sufficient evidence in the published peer reviewed medical literature supporting the use of home-based, real-time surveillance systems." <u>Id</u>.
- 57. CIGNA reaffirmed its clear and unequivocal finding of the clinical utility and non-experimental, non-investigational status of OCT in similar coverage policies issued in 2008, 2009, 2010 and 2011. Such policies govern all standard CIGNA health plans and provide guidance for CIGNA's administration of employer health plans, administered by CIGNA.
- 58. CIGNA issued the 2011 CEM Policy in or about July 2011. The 2011 CEM Policy stated that: "CIGNA covers an external home-based, real-time continuous attended cardiac monitoring system (CPT code 93228, 93229) as medically necessary" when there is a "clinical suspicion of a significant arrhythmia," and "symptoms of syncope, presnycope or severe palpitations" are met. CIGNA described OCT systems as "promoted for use as alarm systems for long-term monitoring in patients" so that "[p]hysicians can monitor a patient's cardiac rhythm for weeks."
- 59. CIGNA cited to and described "published peer-reviewed medical literature supporting the clinical utility" of OCT, including specifically studies involving patients using CardioNet devices and patients using LifeWatch devices. The 2011 CEM Policy also relied on

the FDA's pre-market approval of OCT devices, and specifically identified CardioNet and LifeWatch ACT as manufacturers of approved real-time continuous attended cardiac monitoring systems.

60. The 2011 CEM Policy, like every CEM policy CIGNA issued since 2007, confirmed that: "There is sufficient evidence in the peer-reviewed medical literature supporting the clinical utility of home-based, real time surveillance systems for a specific subset of individuals." In further describing the clinical utility of OCT, the 2011 CEM Policy stated:

Cardiac arrhythmias or abnormal heartbeats represent a major source of morbidity and mortality among patients with cardiovascular disease. While some patients with arrhythmias may experience palpitations, weakness, dizziness, or syncope, other patients may have no symptoms at all. Some arrhythmias pose a significant health threat and require prompt treatment. Treatments for arrhythmias include medical therapy, artificial pacemakers, implanted cardiac defibrillators, and ablation of malfunctioning cardiac tissue. Effective treatment of arrhythmias requires an early diagnosis. This can be difficult, since arrhythmias can occur infrequently and unpredictably and may be asymptomatic. Therefore, devices that monitor a patient's heartbeat for an extended period of time and can automatically detect certain arrhythmias are desirable (ECRI, 2010) (emphasis added).

Id. at p. 2.

- 61. To that end, the 2011 CEM Policy provided for coverage of OCT for all patients with:
 - clinical suspicion of a significant arrhythmia
 - symptoms of sycope, presycope, or severe palpitations occurring less frequently than once per 24 hour represent
 - non-diagnostic 24-hour Holter or non-real time monitoring (e.g., event monitor, pacemaker telephonic telemetry, post-symptom patient-activated recorder or auto-trigger) within 45 days prior to consideration of the use of a home-based real-time continuous attended cardiac monitoring system.

- 62. CIGNA's 2011 CEM Policy also is consistent with and required by the definition of "Medical Necessity" included in CIGNA's national class action settlement in In re: Managed Care Litigation, S.D. Fla. MDL No.: 1334, which adopted the AMA's Prudent Physician standard.
- 63. From June 2007 through September 2012, Plaintiffs routinely billed CIGNA and CIGNA routinely covered charges for equivalent OCT services provided to participants in standard CIGNA health plans and other employer health plans administered by CIGNA as long as the service was "medically necessary" for the individual patient.
- 64. Since the outset of Plaintiffs' contracts with CIGNA, tens of thousands of patients with health insurance underwritten or administered by CIGNA received OCT as a medically necessary, "Covered Service" from LifeWatch and CardioNet. Throughout this same period, Plaintiffs provided OCT services, covered by insurers nationally to hundreds of thousands of patients, all on the orders of cardiologists and other treating physicians.

CIGNA's Reversal of Course and Denial of Coverage for OCT

- 65. In the 2011 CEM Policy, CIGNA set April 15, 2013 as the "next review date." Well before that date, however, CIGNA, in or around July 2012, released a 2012 CEM Policy, which was effective October 15, 2012.
- 66. The 2012 CEM Policy stated that CIGNA "does not cover an external mobile outpatient cardiac telemetry system (CPT code 93228, 93229) for any indication because it is considered experimental, investigational or unproven."
- 67. In support of this conclusion, CIGNA cited to and relied on the exact same body of "published peer-reviewed medical literature" it previously characterized as "sufficient evidence" to support the clinical utility of OCT as its basis for concluding that "[t]here is a lack

of evidence in the published peer-reviewed medical literature supporting the clinical utility of long-term continuous external unattended cardiac monitoring devices."

68. For example:

- A. In both the 2011 and the 2012 CEM Policies, CIGNA described the Rothman study of MCOT as follows: "During monitoring, clinically significant arrhythmias were detected in 55 (41%) patients in the MCOT Group versus 19 (14%) patients in the Loop Group, a statistically significant difference."
- B. In both the 2011 and the 2012 CEM Policy, CIGNA described the Kadish study of ACT as follows: "Of the 26,438 patients included in the study, 5459 (21%) had arrhythmic events meeting physician notification criteria during a mean monitoring period of 21 days. Of these, 262 patients (1%) had arrhythmic events that could potentially be classified as emergent."
- C. Both Policies also cited to the 2005 Joshi study of MCOT. That study not only detected arrhythmias in over half the patients studied, but found that treating physicians had significantly modified their management of these patients including (without limitation) through the initiation of and changes in drug treatments, and insertions of permanent pacemakers and implantable cardiac defibrillators on the basis of the OCT diagnostic data.
- 69. The sole purported clinical justification CIGNA has given Plaintiffs for the 2012 CEM Policy reversal was the statement therein that further studies are required to evaluate how OCT "can change treatment management and improve health outcomes."
- 70. However, the 2011 CEM Coverage Policy and earlier CEM policies included the exact same observation ("additional studies are required to evaluate how real-time surveillance systems may improve health outcomes") while simultaneously concluding that existing peer-reviewed publications and FDA approval justified coverage of OCT.

71. CIGNA has also acknowledged orally and in writing that it has never similarly required medical "outcome" studies in finding that Holter monitors or other CEM services are not considered EIU.

Unsuccessful Efforts to Contest CIGNA's Denial of Coverage for OCT Health Benefits

- 72. Prior to the October 2012 effective date, LifeWatch and CardioNet both communicated with CIGNA's Senior Medical Director of Emerging Technology and Coverage Policy (hereinafter described as "CIGNA Medical Director") to express their opposition to the 2012 CEM Policy.
- 73. In telephonic communications, the CIGNA Medical Director initially claimed that the reversal of OCT coverage was based on medical facts, and that the published peer-reviewed medical literature demonstrated that OCT was unproven.
- 74. When pressed to identify any studies or medical literature on which CIGNA had relied to support its reversal of field, however, the CIGNA Medical Director admitted that CIGNA's change of position was not based on any new or intervening medical studies.
- 75. The Medical Director also acknowledged in so many words that the adoption of the restrictive 2012 CEM Policy was based on economic factors, not on any medical evidence contradicting the CIGNA's previous findings about the clinical utility of OCT coverage.
- 76. In letters to CIGNA's President/CEO through their respective legal counsel, CardioNet and LifeWatch, each sought to have CIGNA reverse its 2012 determination to deny coverage for OCT as of October 15, 2012. Those letters cited, among other things, to the FDA approval of OCT; long-standing coverage by the Medicare program and other major third party payers; CIGNA's 2011 own Coverage Policy statements validating the non-experimental

or investigational status of OCT; the medical literature cited in the 2011 Policy in support of OCT; and the absence of any negative intervening medical literature.

- 77. CardioNet's letter also observed that CIGNA has ignored more recent medical literature, and that CIGNA's putative reliance on the absence of long-term "outcome studies" could not rationally justify a change in policy since the 2011 CEM policy, which approved OCT coverage, included the exact same observation about the absence of long term outcome studies. CardioNet also pointed out that CIGNA had never required or suggested the need for such outcomes studies as a precondition to finding that older diagnostic technologies, such as Holter monitors and event monitors, were "not" considered EIU.
- 78. By letters dated October 2 and 11, 2012, respectively, CIGNA rejected Plaintiffs' requests for reconsideration of its refusal to cover OCT. CIGNA did not respond directly to any of the points raised by CardioNet or LifeWatch but remained firm that: "We cannot agree to withdraw or delay the effective date of the new Coverage Policy."
- 79. CIGNA's responses also "acknowledge[d] this conclusion differs from the conclusions expressed in CIGNA's prior Coverage Policies on the subject," and conceded that "the new Coverage Policy's position will very likely lead to adverse financial consequences" and "will very likely impact [Plaintiffs'] reimbursement."

The August 2012 Physician Updates

80. In August 2012, CIGNA issued a Medical Coverage Policy Updates for Health Care Professionals (the "Physician Updates"). The Physician Updates stated that, effective October 22, 2012: "We will not cover an external mobile outpatient cardiac telemetry system (CPT codes 93228 and 93229) for any indication because it is considered EIU (Experimental, Investigational, and Unproven)."

- 81. On information and belief, CIGNA directed to this update to hundreds of thousands of its network physicians, including without limitation cardiologists, internists, radiologists and pediatricians.
- 82. The Physician Updates for OCT has caused and will continue to cause physicians not to order OCT for patients with CIGNA insurance.
- 83. The Physician Updates has caused and continues to cause physicians to refrain from ordering OCT for patients whose employer plans are more liberal than, and do cover OCT, which undermines Plaintiffs' contractual rights to be compensated for Covered Services, and simultaneously jeopardizes patients with clinically significant arrhythmias for whom OCT is medically necessary.
- 84. Because physicians do not contract with CIGNA on an exclusive basis, the adverse impact of CIGNA's disparaging characterizations of OCT is likely to result in physicians not ordering OCT services for non-CIGNA patients as well as for CIGNA patients.
- 85. By letter dated October 19, 2012, CardioNet demanded that CIGNA withdraw and rescind the portion of the Physician Updates, of which CardioNet had only recently become aware. CardioNet objected, *inter alia*, to CIGNA's characterization of OCT as being "considered EIU," and warned of the harm and injury to CardioNet from that characterization.
- 86. CardioNet also observed out that the strongly and unequivocally worded statement in the August 2012 Physician Update that CIGNA would not cover OCT services "for any indications" conflicted with CIGNA's own acknowledgment in the 2012 CEM Policy that CIGNA's decision not to cover OCT under its own policies would be trumped in the event of conflict with the coverage policies included in employee benefit plans administered by CIGNA.
 - 87. In this regard, the 2012 CEM Policy relevantly states that:

- ... the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies (emphasis in original).
- 88. CIGNA did not respond to or otherwise address CardioNet's October 19, 2012 letter, and has not rescinded or corrected the Physician Updates.
- 89. CIGNA also has been aggressively denying claims OCT services rendered prior to the stated effective dates of either.
- 90. After CIGNA initially had denied over 50 of LifeWatch's ACT claims based on the 2012 CEM Policy for services predating its effective date, a CIGNA employee admitted this action was clearly in error and submitted these claims for reprocessing.
- 91. Thereafter, however, higher level CIGNA officials reversed that corrective action, for most claims, taking the position that CIGNA was free to apply the 2012 CEM Policy for services received prior to its effective date for any claims processed after October 15, 2012.
- 92. In so doing, CIGNA has routinely denied and refused coverage for medically necessary OCT services for which coverage was guaranteed under the 2011 CEM Coverage Policy, even while that policy remained in force and effect.
- 93. On information and belief, CIGNA also has uniformly and arbitrarily denied all claims for OCT pursuant to the 2012 CEM Policy without regard to whether the claims arise under an ERISA plan containing more liberal coverage standards than the 2012 CEM Policy (for example, a plan deeming any service approved by the FDA and assigned a CPT code by the AMA not to be experimental or investigational).

Assignment of Rights and Claim to Plaintiffs

- 94. Because they have a contractual right as in-network providers to direct payments for all Covered Services they supply CIGNA plan members, CIGNA effectively has assigned the right to payment for patients' claims to Plaintiffs.
- 95. Additionally, Plaintiffs each have obtained assignments of claims and rights, including without limitation the right to pursue legal actions for compensatory and equitable relief, from representative patients for which CIGNA has denied coverage of OCT.
- 96. Plaintiffs continue to accrue assignments of rights for denied OCT claims.

 To date, documentation has been received for OCT claims that include those described immediately below.

Patient BJS

- 97. Patient BJS is enrolled in a CIGNA "Open Access Plus" group health benefits plan for the City of West Palm Beach, Florida, for which CardioNet is an in-network provider.
- 98. BJS received MCOT services from CardioNet from October 25, 2012 until October 30, 2012.
- 99. BJS' claim was denied by CIGNA on or about November 1, 2012, based on the 2012 CEM Policy on the stated basis that OCT service is "not covered because it is considered experimental, investigational or unproven for all indications."
- 100. As its sole justification for its denial of BJS's MCOT claim, CIGNA relied on, and, through the HR department of BJS's employer, supplied a copy of the 2012 CEM Policy.
- 101. CIGNA exercises discretion to render coverage determinations under a delegation of authority from BJS' group health plan and/or the employer.

- 102. On information and belief, CIGNA uniformly applied the 2012 CEM Policy in its sole discretion to preclude and reject OCT claims arising under BJS' plan.
- 103. As a consequence of CIGNA's adverse claim determination, BJS was made financially liable for charges for the OCT services CIGNA refused to cover.
- 104. Because BJS's MCOT benefits claim is governed by the 2012 CEM Policy, administrative appeals from the denial of BJS's MCOT claim would be futile.

Patient EG

- 105. Patient EG is a member of the CIGNA "Open Access Plus" plan, an ERISA group health benefits plan for employees of the American Red Cross, for which CardioNet is an in-network provider.
- 106. EG received MCOT from CardioNet for a service period that commenced on November 7, 2012.
- 107. EG's claim was denied by CIGNA on or about November 20, 2012 on the stated basis that OCT is "not covered because it is considered experimental, investigational or unproven for all indications," which is language derived from the 2012 CEM Policy.
- 108. As justification for its denial of EG's claim, for MCOT, CIGNA relied on, and through the HR department of EG's employer, attached a copy of the 2012 CEM Policy.
- 109. EG's underlying health benefits plan includes substantially the same EIU language as the 2012 CEM Policy, and EG's OCT coverage is controlled by the 2012 CEM Policy.
- 110. On information and belief, CIGNA applied the 2012 CEM Policy in its sole discretion to preclude and reject OCT claims arising under EG's plan.
- 111. CIGNA exercises discretion to render coverage determinations under delegations of authority from the ERISA plan and/or the employer.

- 112. As a consequence of CIGNA's adverse claim determination, EG was made financially liable for charges for the OCT services CIGNA refused to cover.
- 113. Because EG's MCOT benefits claim is controlled by the 2012 CEM Policy, administrative appeals from the denial of EG's MCOT claim, would be futile.

Patient WD

- 114. Patient WD is enrolled in group benefits plan of General Dynamics Corporation which administered by CIGNA under the name of CIGNA Care Network.
- 115. WD received ACT services from LifeWatch for a service period that commenced on November 10, 2012.
- 116. WD's claim was denied by CIGNA on or about November 17, 2012, based on the 2012 CEM Policy on the stated basis that OCT service is "not covered because it is considered experimental, investigational or unproven for all indications."
- 117. WD's underlying benefit plan excludes coverage for "experimental or investigative services," or services that are "educational, or provided primarily for research."
- 118. CIGNA denied coverage based solely on the 2012 CEM Policy, which CIGNA applied to reject WD's ACT claim under WD's ERISA plan.
- 119. CIGNA exercises discretion in rendering coverage determination under delegations of authority from the ERISA plans and/or the employer.
- 120. As a consequence of CIGNA's adverse claim determination, WD was made financially liable for charges for the OCT services CIGNA refused to cover.
- 121. WD's plan does not require an appeal of CIGNA's discretionary coverage decisions to General Dynamics Corporation, and any administrative appeal of the denial of the patient's ACT claim to CIGNA would be futile.

Patient WE

- 122. Patient WE is enrolled in a Medicare Part B and in retiree benefits plan of the State of Illinois administered by CIGNA.
- 123. WE received ACT from LifeWatch for a service period commencing on October 22, 2012.
- 124. WE is enrolled in Part B of Medicare and is WE's primary insurer and which fully approved WE's OCT.
- 125. Despite Medicare's coverage and primary payment, CIGNA denied in full WE's claim for secondary coverage for OCT on or about December 6, 2012 based on the 2012 CEM Policy on the stated basis that OCT service is "not covered because it is considered experimental, investigational or unproven for all indications."
- 126. WE's benefits plan includes a more liberal (less extensive) exclusion of EIU services than CIGNA's 2012 CEM Policy; CIGNA nevertheless reflexively applied the 2012 CEM Policy in denying WE's claim as EIU.
- 127. As a consequence of CIGNA's adverse claim determination, WE was made financially liable for charges for the OCT services not covered by Medicare and which CIGNA refused to cover.
- 128. Because WE's ACT benefits claim as adjudicated by CIGNA is controlled by the 2012 CEM Policy, any administrative appeal of the denial of the patient's ACT claim would be futile.

Patient LT

129. Patient LT has primary insurance coverage under Medicare Part B and also is enrolled in a CIGNA Open Access medical plan through the Bi-State Development Agency d/b/a Metro.

- 130. LT received ACT from LifeWatch for a service period commencing on October 22, 2012.
 - 131. Medicare fully approved LT's OCT.
- 132. Despite Medicare's coverage and primary payment, CIGNA denied LT's claim for OCT on or about November 20, 2012 based on the 2012 CEM Policy on the stated basis that OCT service is "not covered because it is considered experimental, investigational or unproven for all indications."
- 133. LT's benefits plan expressly precludes services considered EIU by CIGNA.
- 134. As a consequence of CIGNA's adverse claim determination, LT was made financially liable for charges for the OCT services not covered by Medicare and which CIGNA refused to cover.
- 135. Because LT's ACT benefits claim as adjudicated by CIGNA is controlled by the 2012 CEM Policy, any administrative appeal of the denial of LT's ACT claim, would be futile.
- 136. Over and above the fact that payments for covered services are automatically assigned to Plaintiffs, as in-network providers, by CIGNA. Each of the above-named patients has assigned to CardioNet and/or LifeWatch his/her claims and rights related to reimbursement or coverage of OCT, including specifically, but without limitation the right to file suit for coverage and related relief under ERISA.
- 137. Each such "assignment includes, but is not limited to, the right to ... sue for legal and/or equitable relief regarding the benefit, the payment and/or the reimbursement for the cardiac monitoring services."

138. Under the terms of each assignment, each participant, to the extent allowable, "remains liable to CardioNet/LifeWatch for payment of any amount not paid" by CIGNA for OCT.

COUNT I

ERISA SECTION 502(a)(1)(B) (Coverage of Benefits: Compensatory Relief)

- 139. Plaintiffs incorporate herein all of the preceding paragraphs of this Complaint.
- 140. CIGNA's 2012 CEM Policy and Physician Updates uniformly deny OCT health benefit to ERISA health plan participants whose claims have been assigned to Plaintiffs.
- 141. CIGNA's denial of OCT benefits to these participants and to all others similarly situated ERISA plan participants and beneficiaries is arbitrary and capricious, and constitutes an abuse of discretion because, among other things, it draws the opposite conclusions from the same peer-reviewed literature on which CIGNA based its prior determinations that OCT was not EIU.
- 142. ERISA Section 502(a) (1) (B), 29 U.S.C. §1132(a) (1) (B) authorizes a civil action "to recover benefits due."
- 143. As assignees of plan participants and beneficiaries, Plaintiffs are entitled under ERISA Section 502(a) (1) (B) to recover the OCT benefit that has been denied by CIGNA.
- 144. Plaintiffs' interests in pursuing coverage of OCT for the ERISA plan participants also are inextricably intertwined with those of the individual plan participants.
- 145. Because of their resources, knowledge and expertise about OCT services, Plaintiffs are better suited to challenge CIGNA's adverse coverage decisions on behalf of individual plan participants than would be by virtually any individual plan participant.

Conversely, the costs and requisite medical expertise necessary for challenging the 2012 CEM

Policy present significant practical impediments to patients seeking to do so individually.

146. CIGNA's position on OCT coverage has been set in stone. Among other

things, the Physician Updates states without qualification that "[w]e will not cover an external

mobile outpatient cardiac telemetry system (CPT codes 93228 and 93229) for any indication

because it is considered EIU." In the October 2, 2012 denial of CardioNet's request for

reconsideration of the 2012 CEM coverage change, CIGNA stated that it "cannot agree to

withdraw or delay the effective date of the new Coverage Policy."

147. Given CIGNA's blanket denial of all OCT benefits as a matter of

corporate policy and its flat and repeated refusals to reconsider the 2012 CEM Policy at the

highest corporate levels, it would be futile for the ERISA plan participants whose claims have

been assigned to Plaintiffs to exhaust individual administrative appeals.

148. ERISA Section 502(g) (1), 29 U.S.C. §1132(g), authorizes the award of

reasonable attorneys' fees and costs to a prevailing plaintiff.

WHEREFORE, Plaintiffs request that the Court reverse CIGNA's arbitrary,

capricious and abusive denial of the OCT benefit, order CIGNA to pay Plaintiffs for all assigned

OCT benefits prescribed by the participants' physician at Plaintiffs' contractual rates, and award

Plaintiffs their attorneys' fees and costs incurred in bringing this action, along with any other

relief that the Court deems just.

COUNT II

ERISA Section 502(a) (3)

(Coverage of Benefits: Injunctive Relief)

149. Plaintiffs incorporate herein the preceding paragraphs of this Complaint.

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- 150. CIGNA's blanket denials of OCT benefits will impose financial obligation upon and cause irreparable harm in the form of increased health risk for the above-named ERISA plan participants, and for all others who are similarly situated.
- 151. In its 2012 Revised CEM Coverage Policy denying coverage for OCT, CIGNA acknowledged that undetected "cardiac arrhythmias ... represent a major source of morbidity and mortality among patients with cardiovascular disease," the importance of early diagnosis of serious arrhythmias, and OCT's superiority in detecting "clinically significant arrhythmias" when compared to Holter monitors or conventional cardiac event monitors.
- 152. As a result of CIGNA's 2012 CEM Policy changes, many physicians have ceased ordering, and will not order OCT for their patients covered by health insurance plans underwritten or administered by CIGNA.
 - 153. Many patients will not use OCT if they bear financial responsibility for it.
- 154. Without injunctive relief (at least until the Court resolves Plaintiffs' requests for Declaratory Relief against the 2012 CEM Policy and Physician Updates), thousands of participants and beneficiaries enrolled in ERISA plans underwritten and/or administered by CIGNA may not receive OCT services and will be subjected to serious medical risk due to potentially clinically significant, but undiagnosed cardiac arrhythmias.
- 155. ERISA Section 502(a)(3), 29 U.S.C. §1132(a)(3), authorizes a civil action for injunctive relief against a plan or for "other appropriate equitable relief."
- 156. The elements for consideration of injunctive relief balance in favor of granting injunctive relief.
- 157. As assignees of the participants, Plaintiffs seek the entry of an injunction that (A) orders CIGNA to withdraw the portion of the 2012 CEM Policy withdrawing coverage for OCT services (CPT Code 93228 and 93229) and to provide written notice of that withdrawal

to all who received the 2012 CEM Policy, and (B) orders CIGNA to withdraw and rescind the Physician Updates regarding OCT services and notify in writing all health care professionals or other persons who received the Physician Updates that CIGNA will continue to cover OCT in accordance with the 2011 CEM Policy, which Injunction Order will remain in effect until the Court decides Plaintiffs' claims for Declaratory Relief.

WHEREFORE, Plaintiffs request the Court enter the above equitable relief along with attorneys' fees and costs under 29 U.S.C. § 1132(g) and any other relief that the Court deems just.

COUNT III

ERISA Section 502(a)(3) (Injunctive Relief to Remedy Breach of Fiduciary Duty)

- 158. Plaintiffs incorporate by reference the preceding paragraphs of the Complaint.
- 159. In exercising discretion over coverage determinations, CIGNA is a fiduciary within the ambit of ERISA Section 404(a), 29 U.S.C. § 1104(a)(1) for all ERISA plans referenced in the Complaint.
- 160. CIGNA is required under ERISA to discharge its fiduciary duties "solely in the interest of plan participants and beneficiaries," and "in accordance with the documents and instruments governing the plan under which it renders health benefit coverage determinations."
- 161. The 2012 CEM Policy itself acknowledges that the 2012 CEM Policy is inapplicable when it conflicts with the terms of an applicable plan document.
- 162. On information and belief, CIGNA routinely rejects claims for OCT by plan participants pursuant to the 2012 CEM Policy without regard to and in derogation of the controlling coverage provisions of the ERISA plans for which it serves in a fiduciary role.

- 163. CIGNA has breached its fiduciary duty by failing and refusing to adjudicate OCT claims in accordance with the terms and conditions of the ERISA plans it administers, and by inconsistently applying the EIU standard, despite the absence of any intervening medical evidence to justify that behavior.
- 164. As assignees of plan participants and beneficiaries, Plaintiffs are entitled under ERISA Sections 502(a)(3), 29 U.S.C. § 1132 (a)(3) to injunctive relief against CIGNA's breach of its duty to determine OCT coverage for plan participants and beneficiaries based strictly on the terms of the ERISA plans it administers.

WHEREFORE, Plaintiffs request the award of permanent and interim injunctive relief in the form of an Order requiring CIGNA to process claims for OCT benefits in all instances based on the terms of the ERISA plans for which CIGNA administers coverage claims, and to cease and desist from processing such ERISA claims based on any conflicting terms or standards contained in the 2012 CEM Policy, along with any other relief the Court deems just.

COUNT IV

Breach of Assigned Contracts and Declaratory Relief Under Common Law (Jury Demand)

- 165. Plaintiffs incorporate herein the preceding paragraphs of the Complaint.
- 166. CIGNA has denied coverage of OCT services for CardioNet patients and for LifeWatch patients described in the preceding paragraphs of the Complaint.
- 167. In each of the above cases, CIGNA has breached its contractual obligation to cover medically necessary services under the relevant group health insurance agreement between CIGNA and the patient.
- 168. For each of the cases, CardioNet and LifeWatch, respectively, has obtained from each named patient an assignment of benefits, rights and claims against CIGNA.

- 169. To the extent any of the assigned claims do not arise under or are exempt from ERISA, Plaintiffs, as assignees of the insureds, have a common law contractual right to seek relief against CIGNA on the aforementioned assigned claims under which Plaintiffs "stand in the shoes" of the patients.
- 170. Plaintiffs additionally are statutorily entitled to pursue claims arising out of CIGNA's breach of its contract with the patients/assignors pursuant to 13 Pa. C.S.A. § 2210(b).

WHEREFORE, Plaintiffs request that the Court declare that CIGNA has violated its contractual obligations to cover medically necessary health care services to all such patients by applying the 2012 CEM Policy to deny coverage for OCT for such patients, and award Plaintiffs monetary damages based on the rates prescribed by their respective ASAs with CIGNA for such services, plus consequential and incidental damages, interest, attorney's fees and costs incurred in bringing this action, along with any other relief that the Court deems just.

COUNT V

Tortious Interference With Business Relationships (Jury Demand)

- 171. Plaintiffs incorporate herein the preceding paragraphs of the Complaint.
- 172. As providers of OCT and related services, CardioNet and LifeWatch each individually has economic and business relationships with physicians who have ordered and who may in the future order MCOT or ACT, respectively.
- 173. CardioNet and LifeWatch each individually has a valid business expectancy resulting from these relationships that provides economic benefits to CardioNet and LifeWatch, respectively.
 - 174. CIGNA has been and is aware of these business relationships.

- 175. As a result of CIGNA's issuance of its Physician Updates, in which CIGNA falsely referred to OCT as being "considered experimental, investigational or unproven," and broadly instructed that OCT will not be covered "for any indication," CIGNA has intentionally influenced physicians with whom CardioNet and LifeWatch each has a valid business relationship to refrain from ordering OCT from them.
- 176. At no time did CIGNA have, nor does CIGNA presently have, any privilege or justification for interfering with these relationships.
- 177. As CIGNA already has acknowledged, CIGNA's actions have caused and will continue to cause pecuniary harm to CardioNet and LifeWatch.
- 178. CIGNA's issuance of the 2012 CEM Policy, as well as its Physician Updates, constitutes tortious interference with CardioNet and LifeWatch's current and prospective business relationships.
- 179. The injuries Plaintiffs suffer as a result of the 2012 Policy Updates are not limited to a loss of referrals of CIGNA patients, since the same physicians who participate in CIGNA's network also treat patients enrolled in plans sold or administered by other insurers, so that CIGNA's adverse characterizations of OCT is likely to broadly deter physician orders of OCT.
- 180. Because many physicians, both inside and outside of the CIGNA network, refrain from ordering OCT for their patients, the pecuniary damages resulting to Plaintiffs resulting from CIGNA's activities will be difficult, if not impossible, to prove to a reasonable certainty because it would be difficult, if not impossible, to identify the instances in which this decision occurs.

181. The reputational injuries to CardioNet and LifeWatch resulting from CIGNA's false statements and the resulting interference is difficult, if not impossible, to quantify.

WHEREFORE, Plaintiffs requests that the Court award Plaintiffs monetary relief, including compensatory and punitive damages to remedy Defendant's tortious interference with Plaintiffs economic relationships and the losses of business resulting therefrom, and enter injunctive relief in the form of an Order requiring CIGNA to rescind and withdraw all publications of the above described statements, including its 2012 CEM Policy and the Physician Updates, and award any further relief that the Court deems just and proper.

COUNT VI

LANHAM ACT SECTION 43(a)

- 182. Plaintiffs incorporate herein the preceding paragraphs of this Complaint.
- 183. Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), provides a civil right of action to any person against whom "commercial advertising or promotion, [that] misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities," is used in interstate commerce.
- 184. On information and belief, CIGNA distributed the Physician Updates to millions of physicians across the country via interstate commerce.
- 185. The Physician Updates comprises commercial advertising or promotion, and is misleading and deceptive both in declaring that OCT "is considered EIU," and in conveying the false impression that OCT is never covered under any health plan administered by CIGNA.

- 186. In contrast, with the Physician Updates, the underlying 2012 CEM Policy underscores that CIGNA must cover OCT for patients under plans with more liberal coverage policies than the 2012 CEM Policy.
- 187. The statements contained in CIGNA's Physician Updates will deceive or have a tendency to deceive a substantial portion of CIGNA's target audience, i.e., physicians who would otherwise prescribe OCT.
- 188. The false and misleading statements contained in the 2012 Policy Updates, moreover, will dissuade physicians who receive that publication from prescribing OCT to all patients, not just those insured by or through CIGNA.
- 189. OCT is not actually "considered EIU," as evidenced by, *inter alia*, the fact that CIGNA itself covered OCT for at least five years before issuing the 2012 CEM Policy, by Medicare's longstanding recognition and coverage of OCT, and by the fact that OCT has been FDA approved for over a decade.
- 190. The deception caused by CIGNA's dissemination of the unqualified statements in the Physician Updates that OCT "is considered EIU" is material in that it dissuades physicians who receive the same from prescribing OCT services.
- 191. CIGNA has admitted that the 2012 CEM will cause CardioNet financial damage. The conceded damage caused by the 2012 CEM Policy was further compounded when, in August, 2012, CIGNA issued its widely distributed Physician Updates.
- 192. Because CIGNA caused the 2012 Revised CEM Coverage Policy and the Physician Updates to be widely disseminated to tens of thousands of physicians nationwide, it is difficult, if not impossible, to accurately quantify the harm that the false and misleading statements contained in those documents have caused.

- 193. The reputational harm and loss of good will resulting to Plaintiffs from CIGNA distributing the false and misleading statements is similarly difficult, if not impossible, to quantify.
- 194. Section 35(a) of the Lanham Act, 15 U.S.C. 1117(a), entitles a prevailing party to recover the actual damages sustained as a result of a defendant's violation of 15 U.S.C. 1125(a), and permits the Court to award reasonable attorney fees.
- 195. Section 34(a) of the Lanham Act, 15 U.S.C. § 1116(a), grants the court power to enter injunctions upon such terms as the court shall deem reasonable to prevent a violation under, *inter alia*, Section 43(a) of the Lanham Act.
- 196. Injunctive relief is necessary and legally appropriate in this case to prevent ongoing violations of Section 43(a) of the Lanham Act.

WHEREFORE, Plaintiffs request that the Court enter an Order requiring CIGNA to rescind and withdraw the Physician Updates and to issue corrective advertising to all persons who received the Physician Updates, confirming that OCT is not generally "considered EIU" and that OCT services may be covered under a variety of health plans administered by CIGNA, and award Plaintiffs pecuniary damages suffered as a direct result of CIGNA's dissemination of the above described statements, along with any further relief that the Court deems just and proper.

COUNT VII

Trade Disparagement (Jury Demand)

- 197. Plaintiffs incorporate herein the preceding paragraphs of the Complaint.
- 198. CardioNet and LifeWatch each has the right to compete in the marketplace without being the subject of trade libel.
- 199. CIGNA has repeatedly made statements that OCT "is considered to be experimental, investigational and unproven."

- 200. CIGNA's statements that OCT is EIU are statements of fact and are false.
- 201. CIGNA made these statements knowing they were false, or with reckless disregard of the truth.
- 202. CIGNA has published these statements in both its 2012 CEM Policy and its Physician Updates which, on information and belief, was transmitted to hundreds of thousands of physicians and CIGNA insureds.
- 203. As CIGNA has already acknowledged, these statements have caused, and will continue to cause pecuniary harm to Plaintiffs.
- 204. These statements have damaged, and will continue to damage, CardioNet and LifeWatch's individual reputations to the extent that future loss of business is certain.
- 205. The reputational injury resulting to CardioNet from CIGNA's false statements is difficult, if not impossible, to quantify.
 - 206. CIGNA's false statements constitute trade libel.

WHEREFORE, Plaintiffs request that the Court award Plaintiffs compensatory and punitive damages, and enter injunctive relief against CIGNA in the form of an Order requiring CIGNA to rescind and correct all publications containing the above described false and defamatory statements, and any further relief that the Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following relief:

A. An Order requiring CIGNA to pay/reimburse Plaintiffs for OCT services provided since the implementation of, and derived or not ordered as a result of the 2012 CEM Policy;

B. An Order enjoining CIGNA from applying the 2012 CEM Policy as a

basis for denying coverage for OCT and requiring CIGNA to withdraw and rescind the 2012

CEM Policy;

C. An Order declaring that CIGNA shall cover OCT for the above-noted

assignees and for all other participants of CIGNA's benefit plans whom OCT services are found

to be medically necessary under the terms of the 2011 CEM Policy;

D. An Order requiring CIGNA to withdraw and rescind the Physician

Updates and any other similar communications to third parties in which CIGNA has referred to

OCT as experimental, investigational or unproven;

E. An Order requiring CIGNA to send corrective notices to all persons to

whom it distributed the 2012 Physicians Updates;

F. An award of damages in an amount to be proven at trial in excess of

\$150,000, together with interest;

G. An Order awarding Plaintiffs their costs and attorneys' fees; and

H. Such other and further relief as the Court deems just and proper.

Respectfully submitted,

/s/ Mark H. Gallant

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